

Comparison of urine culture and complete urinalysis results in female patients with suspected urinary tract infection

Complete urinalysis in women with suspected UT

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Abstract

Aim: This study aims to assess the effectiveness of fully automated urine tests by using urine culture results from female patients with suspected urinary tract infections as the reference standard and to determine their practicality for clinicians.

Material and Methods: Chemical and microscopic analysis of urine was performed using a fully automatic urine analyzer (Roche Cobas 6500 u601-u701, Roche Diagnostics GmbH, Mannheim, Germany) in patients with a preliminary diagnosis of symptomatic urinary tract infection who were admitted to xxx University Training and Research Hospital gynecology outpatient clinic between January 2023 and January 2024. Midstream urine samples sent in sterile containers were inoculated on 5% sheep blood agar and EMB agar with a 0.001 caliber core and incubated at 37°C for 18-24 hours under aerob conditions. According to complete urinalysis, leukocyte count ≥ 5 and bacterial count ≥ 1 were considered positive, leukocyte esterase positivity and nitrite positivity were considered positive.

Results: *Escherichia coli* (E.coli), *Streptococcus agalactiae*, *Klebsiella pneumoniae*, *Staphylococcus saprophyticus* and *Candida* spp. were most frequently isolated from a total of 295 urine cultures. The most effective antibiotics against the isolated E.coli strains were nitrofurantoin, fosfomycin, imipenem, meropenem and amikacin. When culture results were taken as gold standard, the diagnostic sensitivity, specificity and accuracy rates of leukocyte esterase and nitrite positivity were 78.3%, 44%, 52.1%, 24.1%, 99.9%, 82.1% for leukocyte esterase and nitrite, respectively.

Discussion: We think that nitrite positivity may be a guide for unnecessary urine culture requests, but urinalysis parameters should not be used instead of culture due to their low accuracy rates.

Keywords

Urine Culture, Urinalysis, E.Coli, Sensitivity, Accuracy

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Introduction

Urinary tract infections are the most common infections in the community, which can range from asymptomatic cystitis to clinics with severe symptoms and are mostly caused by bacteria [1]. Approximately 10-35% of women experience urinary tract infections at some point in their lives. Asymptomatic bacteriuria is frequently detected in 2-7% of pregnant women and it has been suggested that this condition is associated with preterm delivery and pyelonephritis [2]. Diagnosis and treatment of urinary tract infections are of great importance. In urinary tract infections, complaints such as pollacuria, sudden urinary urgency, dysuria, slowing of urinary flow, nocturia, suprapubic and/or lumbar pain may be observed [3]. Laboratory findings include pyuria, bacteriuria, leukocyte esterase positivity, nitrite positivity and the growth of pathogenic bacteria in urine culture, which is considered the gold standard [4, 5]. Urine culture results require 24-48 hours for visualization and require more workload than complete urinalysis. Therefore, antibiotic treatment is usually initiated empirically based on clinical symptoms and complete urinalysis results and then it was adjusted according to culture results. In order to initiate appropriate treatment, the accuracy and reliability of complete urinalysis should be high [6]. Such methods are frequently used in routine laboratories because they are easily applicable and inexpensive, and they accelerate the workflow [7]. Broad-spectrum antibiotics such as quinolones, TMP-SMX, cephalosporins, aminoglycosides and cephalosporins are recommended as the first choice in the treatment of urinary tract infections. Quinolones are also not preferred in pregnant women. As in the whole world, antibiotic resistance is developing at increasing rates in our country due to empirical antibiotic use [8]. Studies have reported that there may not always be a positive correlation between pyuria, nitrite and leukocyte esterase positivity detected by urinalysis and growth in culture [9, 10]. In this study, our purpose was to evaluate the performance of fully automated urine tests by accepting the urine culture results of female patients presenting with suspected urinary tract infections as a reference and to evaluate the convenience for clinicians.

Material and Methods

In this study, we retrospectively analyzed data from patients initially diagnosed with symptomatic urinary tract infections who visited the gynecology outpatient clinic at xxx University Education and Research Hospital between January 2023 and January 2024. The hospital information system was used to document complete urine tests and urine culture sensitivity reports for all patients.

Urine samples were first subjected to chemical and microscopic analysis using a fully automatic urine analyzer (Roche Cobas 6500 u601-u701, Roche Diagnostics GmbH, Mannheim, Germany). According to the fully automatic urine analyzer, values with a leukocyte count of ≥ 5 and a bacterial count of ≥ 1 were evaluated as positive, and according to chemical tests, leukocyte esterase positivity and nitrite positivity were evaluated as positive. Urine culture was also studied from urine samples simultaneously with the complete urine test. Midstream urine sent as early as possible (within two hours after collection) in a sterile container was inoculated onto 5% sheep blood agar and

EMB agar with a 0.001 caliber loop and incubated for 18-24 hours at 37°C under aerobic conditions. Growth was evaluated quantitatively. For this study, urine samples with growth of $\geq 5 \times 10^4$ cfu/ml at the end of incubation were evaluated as positive cultures. The growth of 3 or more microorganisms in urine culture was evaluated as contamination. Identification and antibiotic susceptibility studies of the grown microorganisms were performed with the Phoenix 100 (Becton-Dickinson, USA) automated system and were evaluated according to the criteria of The European Committee on Antimicrobial Susceptibility Testing (EUCAST). *Escherichia coli* ATCC 25922, *Pseudomonas aeruginosa* ATCC 27853, *Staphylococcus aureus* ATCC 25923 and *Enterococcus faecalis* ATCC 29212 strains were used for quality control. Specificity, sensitivity, positive predictive values and negative predictive values were calculated to evaluate the diagnostic performances of chemical and microscopic analysis of complete urine examination, taking urine culture positivity as reference.

Urine sample data of 1496 patients who applied to the Gynecology and Obstetrics clinic with a preliminary diagnosis of urinary tract infection were included in the study. Data for which only urine culture or only complete urinalysis was requested were not included in the study.

Statistical Analysis

Statistical analyses were conducted using the MedCalc software (version 20.009; Ostend, Belgium). Descriptive statistics included number, frequency, percentage, arithmetic mean, standard deviation, median, and 25th and 75th percentile values. The Kolmogorov-Smirnov test was employed to assess the normality of numerical data distributions. The Mann-Whitney U test was used for pairwise group comparisons. Urine culture results served as the reference for evaluating urine strip and microscopy parameters in terms of diagnosis. Sensitivity, specificity, positive and negative predictive values, and AUC (Area Under the Curve) values were calculated. Additionally, ROC analysis was performed to determine the areas under the curve for leukocyte microscopy and bacteria values. A significance level of $p < 0.05$ was used for interpreting the results.

Ethical Approval

This study was approved by the Ethics Committee of the Ordu University Non-Interventional Scientific Research (Date: 2024-05-24 No: 45).

Results

1496 complete urinalysis and urine cultures were studied from urine samples taken from patients who applied to the gynecology and obstetrics outpatient clinic. The causative microorganism grew in 295 of these. No growth was observed in the cultures of 961 patients. The urine of 240 patients was evaluated as contaminated. The result of 295 patients in whom growth was detected in the culture was reported as 105 cfu/ml and a single species of bacteria. The most frequently isolated agents were *Escherichia coli* (n: 150), *Streptococcus agalactiae* (n: 36), *Klebsiella pneumoniae* (n: 27), *Staphylococcus saprophyticus* (n: 7) and *Candida* spp. (n: 7), respectively. *E. coli* strains were found to be resistant to 51% (n:78) to ampicillin, 29.3% (n:44) to TMP-SXT, 29.3% (n:44) to ciprofloxacin and levofloxacin, 18% (n:27) to ceftriaxone and cefixime. *Klebsiella pneumoniae* strains

Table 1. Diagnostic accuracy performance of Leukocyte esterase, Nitrite, Leukocyte microscopy (HPF) and Bacteria (HPF) results in fully automated complete urinalysis

	Sensitivity	Specificity	PPV	NPV	Accuracy
Leukocyte esterase	78.30	44.01	30.0	86.9	52.1
Nitrite	24.6	99.89	98.6	81.1	82.1
Leukocyte microscopy (HPF)	65.42	61.56	34.3	85.3	62.5
Bacteria (HPF)	42.37	65.66	27.5	78.8	60.2

PPV; Positive predictive value, NPV; Negative predictive value, HPF; High Power Field

Table 2. ROC analysis of Leukocyte microscopy (HPF) and Bacteria (HPF) results in fully automated complete urinalysis

	Cut-off	AUC (%95 Confidence Interval)	P- Value
Leukocyte microscopy (HPF)	>3	0.660 (0.622 – 0.698)	<0.0001
Bacteria (HPF)	>30	0.539 (0.500 – 0.579)	0.0487

HPF; High Power Field, AUC; Area Under Curve p<0.05 is considered significant

were found to be resistant to piperacillin-tazobactam, 14.8% (n:4) to ceftriaxone, 11% (n:3) to TMP-SXT and fosfomycin. While no fosfomycin resistance was observed against E.coli, fosfomycin resistance was observed in 11.1% (n:3) against Klebsiella pneumoniae. Imipenem and meropenem resistance of E.coli strains was determined as 0.07% (n:1), 0.13% (n:2) nitrofurantoin resistance and 1.2% (n:3) amikacin resistance. Extended Spectrum Beta Lactamase (ESBL) enzyme positivity was found as 18% and 14.8% in Escherichia coli and Klebsiella pneumoniae isolates, respectively. Resistance rates are not given since the number of other isolated microorganisms is low. Sensitivity values for leukocyte esterase, nitrite, leukocyte microscopy and bacterial microscopy are 78.3%, 24.1%, 65.4%, 42.3% and specificity values are 44%, 99.9%, 61.6%, 65.7%, respectively. The positive predictive value of the nitrite test is remarkable with 98.6%. When the culture result is taken as the gold standard, the diagnostic accuracy performance of complete urinalysis results is given in Table 1.

In patients with no growth in culture (n: 961), 35.4% (n: 340) had leukocyte positivity, and in 28.3% (n: 178) of 628 urine samples with leukocyte positivity, causative microorganism growth was detected in urine culture.

In 293 (30.5%) of 961 samples with negative culture results, leukocyte esterase, nitrite, bacteria and leukocyte values, which are indicators of infection in complete urinalysis, were found to be within normal limits. When we examined the 961 samples with negative culture results, only one of the samples was found to be nitrite positive. In only 423 (44%) of the samples with negative culture results, both leukocyte esterase and leukocyte negativity were detected in microscopy.

In the ROC analysis for leukocyte microscopy, the area under the curve (AUC) was found to be 0.660, (CI 95% = 0.622 - 0.698), and for bacterial microscopy, the area under the curve (AUC) was found to be 0.539, (CI 95% = 0.500 - 0.579). The ROC analysis for leukocyte microscopy and bacterial microscopy tests is given in Table 2.

When we evaluated the culture results according to the seasons,

the growth in urine (85/266, 32%) was found to be higher in winter and the growth in urine (55/303, 18%) was found to be lower in autumn.

Discussion

Urinary tract infections (UTIs) are prevalent bacterial infections in women, attributed to factors such as a short urethra, proximity to the rectum, bacterial contamination of the bladder, and inadequate personal hygiene [1]. These infections can range from asymptomatic to severe and potentially fatal cases. Additionally, UTIs contribute to extended hospital stays, significant workforce loss, and economic burdens, emphasizing the importance of timely diagnosis and treatment [11]. Clinicians should initially order a complete urinalysis for symptomatic patients, and if findings such as leukocytes and bacteria in microscopic analysis, or nitrite and leukocyte esterase in chemical analysis, are present, a urine sample should be cultured. The compatibility of urine culture, the gold standard, and complete urinalysis results is crucial for accurate diagnosis. However, studies have indicated that nitrite and leukocyte esterase positivity and leukocyte microscopy may not always align with culture results [9, 10].

Parlaktaş et al. evaluated complete urinalysis and culture results in patients with a preliminary UTI diagnosis and underscored the importance of urine culture for accurate diagnosis and treatment [12]. Our study reviewed the complete urinalysis and culture results of 1,496 patients, revealing that 64.2% of the culture results were negative. Similarly, Kayaalp et al. found that 97.7% of 32,998 samples had negative culture results [13]. Other studies by Martinez et al. and Okada et al. reported negative culture results at rates of 52% and 68.3%, respectively [14, 15]. Hence, complete urinalysis appears crucial before deciding to order a culture.

In our study, Escherichia coli was the most frequently isolated microorganism (51%) in UTIs at Ordu University Training and Research Hospital Gynecology and Obstetrics Outpatient Clinic, followed by Streptococcus agalactiae (12.2%) and Klebsiella pneumoniae (9.2%). Similar findings were reported by Çeken and Avcı (86%), Öner et al. (79.4%), and Sezgin and Nar (71.9%) [16- 17]. The most effective antibiotics against E.coli strains in our study were fosfomycin, imipenem, meropenem, nitrofurantoin, and amikacin [17]. Sezgin and Nar reported high resistance to ampicillin and trimethoprim-sulfamethoxazole in E.coli isolates, a trend also noted globally by Bryce et al., who found high resistance rates to these antibiotics and low resistance to nitrofurantoin [18].

Quinolone antibiotics are commonly used empirically for UTI treatment. Sezgin and Nar reported a 4% quinolone resistance in E.coli, while our study found a 29.3% ciprofloxacin resistance [17]. The highest resistance in E.coli strains was against ampicillin, trimethoprim-sulfamethoxazole, ciprofloxacin, and levofloxacin.

Evaluating the positive and negative predictive values of diagnostic methods aids in UTI treatment. Özer et al. reported these values as 29.9% and 95.3% for leukocyte esterase, 27.6% and 95.6% for leukocyte microscopy, and 80.7% and 93.1% for nitrite [19]. Our study found 30% and 86.9% for leukocyte esterase, 34.3% and 85.3% for leukocyte microscopy, and

98.6% and 81.1% for nitrite, highlighting nitrite's high positive predictive value.

European urinalysis guidelines recommend analytical sensitivity and specificity ranges for leukocyte esterase (80-90%) and nitrite tests (20-80% sensitivity, >90% specificity). Sezgin and Nar reported nitrite test sensitivity and specificity as 17.1% and 99%, respectively, while Yüksel et al. found 17.7% and 90.1% [20]. Our study determined nitrite test sensitivity and specificity as 24.1% and 99.9%, suggesting it as a strong predictor of negative culture results.

Gülcan et al [21]. reported leukocyte esterase sensitivity at 89.3%, specificity at 18.2%, positive predictive value at 55.4%, and negative predictive value at 60.0%. Mokube et al [22]. found leukocyte esterase sensitivity at 20.8%, specificity at 80.8%, positive predictive value at 25%, and negative predictive value at 77%. Our study found leukocyte esterase sensitivity at 78.3%, specificity at 44%, positive predictive value at 30%, and negative predictive value at 86.9%. Sezgin and Nar reported leukocyte and nitrite presence concordance with culture at 88.4% and 69.8%, respectively [17], and Güdücüoğlu et al [22]. reported an 88.25% accuracy rate comparing leukocyte results with culture results. High false negative rates for leukocytes in culture-positive patients may result from the limitations of fully automated urine devices. In our study, leukocyte positivity was noted in 35.4% of culture-negative patients. Factors such as undetected bacteria in routine culture media, urethritis-causing agents (e.g., Chlamydia, Neisseria, Mycoplasma), and antibiotic use should be considered. Our comparison of leukocyte esterase and nitrite results with culture showed accuracy rates of 52.1% and 82.1%, respectively [23].

Yüksel et al [20]. found high sensitivities for leukocyte esterase (86.1%) and leukocyte microscopy (88.0%), and high specificities for nitrite (95.4%) and bacterial (86.6%) examinations. Kayaalp et al [13]. reported the highest sensitivity (78.8%) and specificity (97.8%) for bacterial microscopy, and 68.2% and 87.8% for leukocyte microscopy. Kaçmaz et al. found pyuria sensitivity at 76%, and Özer et al. at 67.8%. Our study found high sensitivities for leukocyte esterase (78.3%) and leukocyte microscopy (65.4%), and high specificities for nitrite (95.9%) and bacterial microscopy (65.7%). In 28.3% (178/628) of pyuria samples, culture showed growth, indicating limited usefulness of pyuria alone for UTI diagnosis.

In 30.5% of samples with negative culture results, leukocyte esterase, nitrite, bacteria, and leukocyte values in complete urinalysis were within normal limits. Among 961 negative culture samples, only one was nitrite positive, and 44% had both leukocyte esterase and leukocyte negativity in microscopy. Yüksel et al [20]. reported an AUC of 0.852 for leukocyte microscopy in ROC analysis, Zorbozan et al [24]. found 0.923 for leukocyte microscopy, and Üzmez et al [25]. reported 0.793 and 0.861 for leukocyte and bacterial counts, respectively. Our study found AUC values of 0.660 for leukocyte microscopy and 0.539 for bacterial microscopy.

Lacking previous antibiotic resistance data for female UTI patients in our province limits our ability to report changes in resistance rates. We also acknowledge the absence of clinical evaluation data as a limitation of our study, despite the preliminary UTI diagnosis being recorded in our hospital's

information system during retrospective evaluation.

Conclusion

In conclusion, urinalysis parameters do not have the precision required to substitute culture tests. As the workload in medical laboratories increases, fully automated urinalysis devices could be beneficial for high-throughput environments. For cost efficiency, positive nitrite results may help in avoiding unnecessary urine cultures. However, negative nitrite results are insufficient to rule out urinary tract infections, making urine culture necessary. Furthermore, leukocyte esterase shows poor diagnostic performance in both identifying and excluding the presence of disease.

Inappropriate antibiotic use has led to increased resistance in many microorganisms. The sensitivity to ampicillin and trimethoprim-sulfamethoxazole is decreasing, making their empirical use risky and potentially ineffective. Conversely, no resistance to nitrofurantoin and fosfomycin was found in urinary tract infections attributed to E.coli, supporting their recommendation for empirical treatment. The growing resistance to quinolones should also be considered. To combat resistance, it is crucial to know the susceptibility rates of microorganisms causing urinary tract infections in our region and to apply our study's findings to enhance treatment success rates.

Limitation

Our study has several limitations that should be acknowledged. First, the data on urinalysis parameters and culture results were collected from a single center, which may limit the generalizability of our findings to other settings or populations. Second, while we evaluated the performance of automated urinalysis devices, our study did not include a direct comparison with manual microscopy, which is a commonly used method in many laboratories. Third, the antibiotic resistance patterns were based on data from a specific time period, and resistance rates can change over time; therefore, ongoing surveillance is necessary. Finally, our study did not assess the clinical outcomes of patients, which would provide more comprehensive insights into the impact of our findings on patient care. Future research should address these limitations by including multicenter data, comparing different diagnostic methods, monitoring resistance trends over time, and evaluating patient outcomes.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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